

expected, diabetes has a negative impact on diabetic patient's quality of life, some variables were identified to contribute to a worst perceived QoL.

PDB47

#### THE SUITABILITY OF POLYCYSTIC OVARY SYNDROME-SPECIFIC QUESTIONNAIRES FOR MEASURING THE IMPACT OF PCOS ON QUALITY OF LIFE IN CLINICAL TRIALS

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**OBJECTIVES:** Previous research has shown that generic patient-reported outcome (PRO) measures underestimate the impact of polycystic ovary syndrome (PCOS) on quality of life (QoL). Following recent regulatory guidance, our review aimed to identify PCOS-specific QoL measures and establish whether their development history and measurement properties support their use in clinical trials. **METHODS:** A systematic search of MEDLINE and PsycINFO was conducted using terms synonymous with "PCOS" in combination with terms associated with "QoL" to identify PCOS-specific QoL measures completed by the patient. Articles were included if written in the English language and published since 1998. Following identification of measures, further searches were undertaken using the questionnaire name and abbreviation to explore its use, development history and demonstrated measurement properties. **RESULTS:** Sixty-five abstracts were identified and screened. Of these, 19 reported quantitative studies using a variety of PRO questionnaires (most commonly the SF-36). Only one PCOS-specific QoL questionnaire was identified: the PolyCystic Ovary Syndrome Questionnaire (PCOSQ). A search for use of the PCOSQ since its development publication (1998) returned ten papers, which were included in our review. The PCOSQ's development history (including conceptual and endpoint models) is inadequate, with recent studies indicating that the PCOSQ does not have good content validity, e.g. the impact of acne on QoL is notably missing. The PCOSQ subscales demonstrate acceptable levels of reliability (0.54–0.93) and partial known-groups validity ( $p < 0.05$  between treatment and placebo groups on three of the five PCOSQ domains) as well as convergent/divergent validity with other PRO instruments. Responsiveness to change has been variable and minimally important differences (MIDs) have not been established. **CONCLUSIONS:** The PCOSQ has dominated research relating to the impact of PCOS on QoL. However, in order to fulfil current regulatory requirements, additional research is required to ensure its comprehensibility and sensitivity prior to including the PCOSQ in a clinical trial programme.

PDB48

#### NOT ALL ROADS LEAD TO ROME—A REVIEW OF QUALITY OF LIFE MEASUREMENT IN DIABETES

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**OBJECTIVES:** Quality of life (QoL) is recognised widely as an important health outcome in diabetes, where the daily burden of self-management places great demands on the individual. However, the concept of QoL remains ambiguous and poorly defined. The aim of our review was to clarify the measurement of QoL in terms of conceptualisation, terminology and psychometric properties, to review the instruments that have been used most frequently to assess QoL in diabetes research and make recommendations for how to select measures appropriately. **METHODS:** A systematic literature search was conducted to

identify the ten measures most frequently used to assess QoL in diabetes research studies and clinical trials from 1995 to March 2008. **RESULTS:** A total of 6,085 abstracts were screened for instrument names. An assessment of content validity indicated that, of the ten instruments most frequently used to assess "QoL", only three actually do so (i.e. the generic WHOQoL, and the diabetes-specific DQOL and ADDQoL). The remaining seven instruments more accurately measure health status (SF-36, EQ-5D), treatment satisfaction (DTSQ) and psychological well-being (BDI, HADS, W-BQ, PAID). In addition, development histories are variable, as is the extent to which psychometric properties have been established in diabetes. **CONCLUSIONS:** No single measure can suit every purpose or application but researchers have repeatedly and erroneously used inappropriate instruments to assess QoL in diabetes. Any conclusions related to QoL drawn from such assessments, therefore, are fundamentally flawed. If we value QoL as a goal of therapy, then we must ensure that the instruments we use to assess effectiveness are both valid and reliable. Investigators need to be clear about exactly what they wish to assess when selecting a measure (matching concept to content) and ensure appropriate interpretation. When a holistic evaluation is required, using two or three brief measures in combination may offer a broader perspective.

PDB49

#### HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND TREATMENT SATISFACTION (TS) IN DIABETIC PATIENTS ATTENDED IN SPANISH PRIMARY CARE CENTRES

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**OBJECTIVES:** To assess the HRQoL and treatment satisfaction in diabetic patients and analyze their relationship with the glycemic control. **METHODS:** An epidemiological, cross sectional, naturalistic study was carried out in Spanish Primary Care centres. Patients >18 years with diabetes mellitus type 1 (T1DM) or type 2, with insulin treatment (T2DM-i) or not (T2DM-n.i), were enrolled in the study (consecutive cases sampling). The last value of glycosylated hemoglobin (HbA1c) of each patient, reported in 2006, defined the glycemic control as satisfactory ( $\text{HbA1c} \leq 7\%$ ) or unsatisfactory ( $\text{HbA1c} > 7\%$ ). HRQoL was obtained from EQ-5D questionnaire and its VAS subscale and TS from the Diabetes Treatment Satisfaction Questionnaire (SATQ-s). Differences between groups were determined by Chi-Square and t-student tests and ANCOVA models. **RESULTS:** A total of 679 patients were enrolled in the study: 52.4% female; age 65.2 (13.7); BMI 28.81 (4.66); type of diabetes: 11.5% T1DM, 26.2% T2DM-i and 62.3% T2DM-n.i; mean time from diagnoses 11.9 (9.25) years. 53% of patients achieved satisfactory control (T1DM: 29.5%, T2DM-i: 31.5% and T2DM-n.i: 63.8%;  $p < 0.001$ ). EQ-5D score were 0.76 (0.22); T1DM group obtained a little higher score, 0.86 (0.18), than T2DM groups ( $p < 0.05$ ) and no differences were found between glycemic control groups. VAS total score was 64.48 (17.93); patients with satisfactory control obtained a higher score, 65.72 (17.72) vs 63.30 (18.22);  $p < 0.05$ . T1DM and T2DM-n.i groups reported a VAS score higher than T2DM-i: 66.41 (17.90) vs. 66.28 (17.33) vs 59.47 (18.48) respectively. SATQ-s total score was 25.01 (6.67); T2DM-n.i group was more treatment-satisfied than T2DM-i and T1DM: 26.15 (5.85) vs 22.97 (7.63) and 23.47 (7.10) respectively. Satisfactory control group also obtained a higher score than unsatisfactory control group:  $25.79 \pm 6.28$  vs  $24.39 \pm 6.88$ ;  $p < 0.05$ . **CONCLUSIONS:** Patients with satisfactory glycemic control obtained better values of HRQoL (VAS)

and TS. T1DM and T2DM-n.i reported better values of HRQoL and T2DM-n.i better TS.

## PDB50

# CONCEPTUAL DEVELOPMENT OF A PATIENT SELF-ASSESSMENT TOOL TO IMPROVE PATIENT-CLINICIAN COMMUNICATION ON THE DAILY MANAGEMENT OF TYPE 2 DIABETES

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**OBJECTIVES:** Patients play a major role in the management of type 2 diabetes since this depends not only on medication but also on behavioural modifications in areas such as nutrition, physical activities and weight loss. Therefore, patients' understanding of the disease and its management are particularly important to ensure high compliance and reduce risk of late complications. The aim of this project was to develop a tool for clinical practice to 1) renew patient-clinician communication on type 2 diabetes management; 2) reinforce patients' motivation by rectifying or perfecting their knowledge; and 3) agree achievable micro-objectives between patients and clinicians. **METHODS:** Face-to-face semi-structured interviews were conducted with 10 adult type 2 diabetes patients by a psychologist in parallel with interviews with 5 general practitioners, involved in the management of type 2 diabetic patients. All interviews were recorded and transcribed, in order to analyse the content and organise it by domains. Based on these findings and on feedback from experts, a first version of the tool was developed. This was tested using a cognitive interview method with 5 type 2 diabetics, to assess the clarity, comprehension, and relevance of each item as well as the overall acceptability of the tool. **RESULTS:** Five major domains were identified as playing a role in type 2 diabetes disease management: physical activities, treatment, nutrition, knowledge of the disease and knowledge of glycaemia issues. A specific module was developed around each of the 5 domains, drafting items using patients' verbatim expressions. The tool allows patients to describe their beliefs, attitudes and priorities. The tool was revised after the patient tests. **CONCLUSIONS:** This tool should enhance patient-clinician communication on diabetes management. By revealing patients' beliefs, identifying their goals, triggering positive changes, this tool could help clinicians with the therapeutic education of patients. It will be tested in a specific validation study.

## PDB51

# UNDERSTANDING AND ASSESSING THE IMPACT OF DIABETES TREATMENT ACROSS MEDICATION DELIVERY SYSTEMS

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**OBJECTIVES:** Diabetes is a common, debilitating chronic illness with multiple impacts on patients' lives. Critical to understanding these impacts is the effect of the treatment delivery system. In diabetes multiple systems are available; however, a patient reported outcomes (PRO) measure assessing impacts appropriate for all systems is not available. As a result, impacts can't be compared across treatments and clinical decisions targeting treatments to patient needs is hampered. A well developed PRO

measure appropriate across delivery systems is critical for future research. The purpose of the study was to understand the full spectrum of PRO issues and develop a measure of these impacts across all delivery systems. **METHODS:** Qualitative data was collected from literature, experts and patients and transcripts thematically coded. Additionally, validation findings from four previously developed diabetes PRO measures (ITSQ, Diab-MedSat, Diabetes Productivity, Diabetes Symptom) were examined for relevance. Based on a synthesis of all information, a conceptual model of the impact of treatment applicable to all delivery systems was developed and a PRO measure generated. **RESULTS:** A total of 143 patients in three countries (US, UK, Australia) treated with the full range of treatment options (oral, syringe, pen, inhaled, pump) were interviewed regarding the impact of diabetes treatment on functioning, well-being and health. Regardless of delivery system, common impacts of diabetes treatment were identified: psychological health, daily life interference (home/work), treatment burden, device satisfaction, perceived efficacy and side effects. Key modifiers to this impact (i.e., treatment history, occupation, activity level) and consequences (i.e., compliance, poor productivity) were also identified. Based on the conceptual model, a PRO impact measure (TRIM-Diabetes) was generated with six discrete domains. **CONCLUSIONS:** The instrument development process, the full conceptual model, and discussion of clinical implications will be presented. This information should help clinicians identify key PRO issues for diabetes, facilitate targeted treatments and allow for meaningful measurement of treatment effect regardless of treatment delivery system.

## PDB52

# A SELF-MANAGEMENT PROFILE FOR PATIENTS WITH TYPE-2 DIABETES

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**OBJECTIVES:** To develop concepts, domains and items for a patient-reported outcome profile measure that addresses the behaviors, attitudes, and importance of self-managing diabetes in patients with type 2 diabetes. This self-management profile complements traditional clinical outcomes to evaluate how diabetes treatments improve self-management behaviors. **METHODS:** We developed a conceptual model and conceptual framework of patient self-management to support a patient-reported self-management profile. These models incorporate treatment attributes identified through qualitative interviews with patients and the review of the American Diabetes Association (ADA) 2008 *Standards of Medical Care in Diabetes*. The profile consists of items measuring patient behaviors, feelings, and attitudes about the importance of managing their blood glucose, medication regimen, weight, eating, exercise, and diabetes-related distress. Qualitative interviews were conducted with patients with Type 2 diabetes managed with combinations of lifestyle, oral and injectable therapy. Subjects were asked to provide information on their most positive and problematic experiences with treatment for their diabetes and their efforts to manage their condition. Qualitative transcripts were coded by like concepts and used with the ADA Standards to generate items and develop the self management profile. Additional patients participated in cognitive interviews to address relevance and clarity of items. **RESULTS:** Patients were enrolled from clinics across the United States. Participants in the concept elicitation interviews (n = 82) were 30–85 years of age (mean = 57.5);